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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/937,834 | 02/13/2002 | Johannes Booij | 246152015300 | 5546 |
| 7590 | 12/10/2003 | | EXAMINER | |
| Kate H Murashige Morrison & Foerster Suite 500 3811 Valley Center Drive San Diego, CA 92130-2332 | | | BERCH, MARK L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | 10 |
| DATE MAILED: 12/10/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/937,834 | BOOIJ ET AL. | |
| | Examiner | Art Unit | |
| | Mark L. Berch | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 October 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-14, 16-20, 25 and 27-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-14, 16-20, 25, and 27-50 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 37-38, 40-42, 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4454069, 6417352, or 5288861.

In 4454069, see column 5, lines 36-39, which refers to Potassium clavulanate in the form of “microcrystals ... well-defined needles or waisted plates. 6417352 gives another crystallization. The form is not stated, but conditions which would be expected to obtain the rosettes were not used. In 5288861, a description of different forms appears at column 1, lines 41-45. For particle size, see column 11, lines 16-40, which discloses the distribution of particle size for conventional needles, which are of course hygroscopic. It can be seen that the average size is somewhere in the 640-1280 range for both samples A and B, meaning that claim 44 but not 43 is anticipated.

The traverse is unpersuasive. Applicants first argue that these e.g. needles are not agglomerates. But that is a very broad term. It simply means a collection or mass, which could be a collection or mass of needles. Indeed, crystals are agglomerates by their very nature. Second, applicants argue that the needles of 4454069 have a density of 0.18. However, a) applicants present no evidence that this is true and 2) the 0.18 would be covered by the “about 0.2”. The same is true for the compressibility.

With regard to 5288861 and 6417352, it is correct that the references are silent on the matter of its e.g. density characteristic, and 4454069 is silent on the particle size characteristic. However, if mere silence were enough, then every anticipation could be overcome by simply putting in some limitation that the reference happened to be silent about, even if the material were exactly the same as the prior art. One could put in a limitation about density, color, melting point, solubility in some obscure solvent, spectroscopic data, and then simply point to the silence of the reference, as applicants have done here. Applicants could insert the limitation "which does not explode upon tapping" and point out the reference says nothing about this limitation at all.

MPEP 2112 states: "A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC"

The section goes on as follows:

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Here, the "function is not explicitly disclosed by the reference" is the compressibility, etc. Applicants need to show that such is not actually present in the reference.

Claims 37-50 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/33564.

In WO97/33564, see the agglomerate at page 10, lines 13-23, and examples 7-11. Other particle size distributions appear at page 5-6. Potassium clavulanate in crystalline form may be presumed, since it is generally available in that form. With regard to claim 22, it is assumed that dependency on claim 6, not claim 5 was intended, since claim 5 does not permit anything else. With regard to claim 23, example 11 has the carrier at page 21, line 8. The traverse is unpersuasive. Much the same reasoning applies here. If applicants wish to argue that the material is "insufficiently free-flowing" they must present evidence to that effect.

Claims 10-14, 16-19, 25, 27-32, 37-38, 42-45. are rejected under 35 U.S.C. 102(b) as being anticipated by Harbridge, Cardoso, WO 98/21212.

The lifting of the requirement for being highly hygroscopic broadens the claims (see description requirement rejection below). Thus, examples such as 18 or 20-21 of Harbridge now anticipate. In Cardoso, see, example 5. In WO 98/21212, see examples 5, 7. Many more references could be cited.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The claim 45 limitation is unclear. Flowability can be measured by one of several different methods, including slump cone, flow cone, or using an open ended high cylinder. Further, "clavulanate needles" is a general term, and different preparations of needles will give different results. It is also unclear how much improvement is needed to qualify.
2. The same is true of compressibility in claim 31. There are different standard techniques, such as MPIF 45, and ASTM B-331. It can be measured under isostatic, uniaxial or multiaxial compaction.

Claims 10-14, 16-20, 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10-14, 16-20, 25, 27-32, 35-45, and 47-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Potassium clavulanate, does not reasonably provide enablement for other clavulanates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims as written say that any clavulanate can be made into a crystalline form just by stirring (claim 10) and perhaps adding a second solvent (e.g. claims 11-14). This is certainly not true. The fact that this procedure works with the Potassium clavulanate is no assurance that this will work with other compounds. The claim language covers e.g. clavulanic acid itself, which is an oil, and esters thereof, which are commonly oils, e.g. the methyl, benzyl and nonyl esters.

Claims 10-14, 16-20, 25, and 27-50 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The removal of dependency on claim 1 has broadened the claims. The previous limitation of "high water affinity", whatever that meant, has been removed, so that applicants are now covering compounds and crystalline forms thereof which are e.g. not hydroscopic at all, which is beyond what the specification teaches is the invention (see page 5, lines 3-6).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

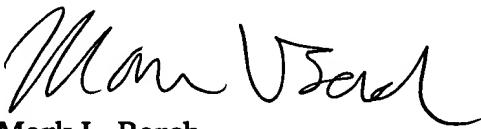
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

December 4, 2003